

Application Number 10/825,953

Responsive to Office Action mailed December 28, 2006

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**REMARKS**

This submission is responsive to the Final Office Action dated December 28, 2006.

Claims 1-12, 14-16, 22-35, 37, 38, 44-47 and 50-77 remain pending.

**Allowable Subject Matter**

The Final Office Action indicated that claims 47 and 50-75 are allowed. The Final Office Action also indicated that claims 17-21, 39-43, 45 and 49 are objected to as being dependent on a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. Applicant appreciates these indications of allowability.

**Claim Rejection Under 35 U.S.C. § 102**

The Final Office Action rejected claims 1-3, 23-26, 44 and 76 under 35 U.S.C. § 102(e) as being anticipated by Park (US 6,881,192). Applicant respectfully traverses the rejection. Park fails to disclose each and every feature of the claimed invention, as required by 35 U.S.C. § 102(e), and provides no teaching that would have suggested the desirability of modification to include such features.

For example, Park fails to disclose or suggest a method comprising comparing a sleep quality metric value to a threshold value and adjusting a therapy parameter within a specified range based on the comparison, as recited by independent claim 1. Similarly, with respect to claim 24, Park fails to disclose or suggest a medical device comprising a processor to compare a sleep quality metric value to a threshold value, and adjust a therapy parameter within a specified range based on the comparison.

Instead, Park describes applying different types of pacing therapy to a patient to determine which therapies are effective at lessening an average apnea duration or total apnea duration. More specifically, a therapy is evaluated by collecting data representing average and total apnea durations during an evaluation timeframe and transmitting the data to a physician for review. Multiple therapies may be evaluated, each during a respective evaluation timeframe, and the physician may select pre-stored or downloaded therapies to evaluate. After apnea duration

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data is collected for multiple therapies, the data is analyzed to determine which therapy is most effective at shortening the apnea duration.<sup>1</sup>

Park does not disclose or suggest comparing a sleep quality metric value to a threshold value and adjusting a therapy parameter with a specified range based on the comparison. As described by Park, after a completed evaluation period for one therapy, a physician selects a next therapy to test during the next evaluation period. Park does not teach or suggest that this selection is based on apnea duration data at all, much less based on a comparison of apnea duration data to a threshold value. For at least these reasons, Park fails to teach or suggest each and every requirement of independent claims 1 and 24.

Furthermore, with respect to independent claim 76, Park fails to disclose or suggest an implantable neurostimulator or an implantable pump. Instead, Park describes an implantable cardiac therapy device. In addition, it seems that the rejection of claim 76 is somewhat inconsistent with the Examiner's indication of allowable subject matter in claim 45.

Park fails to disclose each and every limitation set forth in independent claims 1, 24, and 76. Claims 2, 3, and 23 are dependent upon claim 1, and claims 25, 26, and 44 are dependent upon claim 24. These dependent claims are also in condition for allowance for the reasons stated above with respect to independent claims 1, 24 and 76. For at least these reasons, the Final Office Action has failed to establish a prima facie case for anticipation of Applicant's claims 1-3, 23-26, 44, and 76 under 35 U.S.C. § 102(e). Withdrawal of this rejection is requested.

#### **Claim Rejection Under 35 U.S.C. § 103**

The Final Office Action rejected claims 22, 46, and 77 under 35 U.S.C. § 103(a) as being unpatentable over Park in view of Civelli et al. (US 6,884,596, herein referred to as Civelli). Applicant respectfully traverses the rejection. The applied references fail to disclose or suggest the inventions defined by Applicant's claims, and provide no teaching that would have suggested the desirability of modification to arrive at the claimed invention.

The Final Office Action acknowledged that Park fails to disclose a medical device that delivers a therapy to the patient to treat chronic pain, as required by Applicant's claims 22, 46, and 77. However, the Final Office Action cited Civelli as disclosing that chronic pain reduces

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<sup>1</sup> Park, column 12, lines 14-51 and FIG. 6.

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sleep quality. On this basis, the Final Office Action concluded that it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the medical device described by Park to treat chronic pain. Applicant disagrees with this analysis.

Civelli does not disclose a medical device that delivers therapy to treat chronic pain. Instead, Civelli merely states that chronic pain can cause reduced quality or quantity of sleep.<sup>2</sup>

On the other hand, Park describes detecting sleep apnea events, determining average and overall apnea durations based on the detected events, and delivering pacing therapy to shorten the average and overall apnea durations. Park is focused on treating sleep apnea, and is not concerned with treating any other conditions that affect sleep quality. Since Park is narrowly directed toward treating sleep apnea, it is unclear why one of ordinary skill in the art would even consider modifying Park to deliver therapy to treat chronic pain.

A person of ordinary skill would not have considered Civelli's general teaching that chronic pain affects sleep quality relevant in the context of Park's narrow teachings of treating sleep apnea. Accordingly, such a person would not have been motivated to modify Park to additionally treat chronic pain based on Civelli's teaching.

For at least these reasons, the Final Office Action has failed to establish a prima facie case for non-patentability of Applicant's claims 22, 46, and 77 under 35 U.S.C. 103(a). Withdrawal of this rejection is requested.

**Rejection for Obviousness-type Double Patenting:**

The Final Office Action provisionally rejected claims 1-49 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 2, 5-10, 12-23, 25-29, 32-58, 60-66, and 68 of copending Application No. 10/825,955; claims 1-11, 12, 14, 16-18, 19-30, 32-44, 46-50, 52-57, 59-60, 62-67 and 68 of copending Application No. 10/825,964; claims 1, 3-8, 11-16, 19-24, 26-30, 34-36, 38, 39, 41, 44-48 and 69-76 of copending Application No. 10/825,965; claims 1-11, 16-34, 38-47, 48, 69, 70, 73-79, 83, 84, 87-92 and 96-99 of copending Application No. 10/826,925; claims 1, 3, 8, 9, and 13-15 of copending Application No. 11/081,811; and claims 1-7, 25 and 28-37 of copending Application No. 11/081,873.

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<sup>2</sup> Civelli, column 7, lines 37-41.

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A Terminal Disclaimer accompanies this Amendment. The disclaimer is made to expedite issuance and is not intended as an admission that any claim of the present application is the same or an obvious variant of those of U.S. Application Nos. 10/825,955, 10/825,964, 10/825,965, 10/826,925, 11/081,811, or 11/081,873. This disclaimer obviates the double patenting rejection and places claims 1-12, 14-16, 22-35, 37, 38, 44-47 and 50-77 in a condition for allowance.

### CONCLUSION

All claims in this application are in condition for allowance. Applicant respectfully requests reconsideration and prompt allowance of all pending claims.

In view of the clear distinctions identified above between the current claims and the applied prior art, Applicant reserves further comment at this time regarding any other features of the independent or dependent claims. However, Applicant does not necessarily admit or acquiesce in any of the rejections or the Examiner's interpretations of the applied references. Applicant reserves the right to present additional arguments with respect to any of the independent or dependent claims.

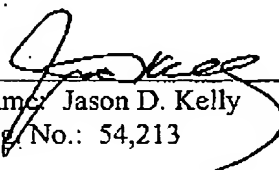
Please charge any additional fees or credit any overpayment to deposit account number 50-1778. The Examiner is invited to telephone the below-signed attorney to discuss this application.

Date:

2/28/07

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